Remarks

Applicants kindly request the Examiner to enter the amendment adding claim 48 as indicated above. No new matter is added by the amendment and support for the amendment can be found in the original specification including in Figures 2 and 3 as well as on page 3, paragraph 19 (in reference to U.S. Patent Application Publication US2006/0251652).

Claims 34-47 are pending in the present application and are subject to the following restriction pursuant to 35 U.S.C. 121 and 372:

Group I, claims 34-39, drawn to antibodies.

Group II, claims 40-47, drawn to methods of treatment.

Applicants hereby elect, with traverse, the invention of Group I (claims 34-39), directed to antibodies. The newly added claim 48 is drawn to an antibody and, therefore, falls within Group I of the Examiner's proposed grouping of the inventions in the application. The Examiner also requested Applicants to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Therefore, Applicants select as the single species to which the claims shall be restricted if no generic claim is finally held to be allowable the antibody comprising a CD20 binding molecule wherein the CD20 binding molecule comprises the AME 33 heavy chain variable region amino acid sequence (SEQ ID NOS: 61). Applicants believe that claims 34-39 as well as new claim 48 read on the elected species.

Applicants respectfully disagree with the requirement for restriction and, in accordance with 37 C.F.R. § 1.143, hereby request reconsideration and withdrawal of the requirement for the following reasons. First, the Examiner alleges that the inventions of Group I and Group II lack a special technical feature "because the antibody of claim 34 appears to have been known in the art." (page 2 of the Office Communication; emphasis added) The basis for the Examiner's contention is a January 3, 2003 press release by AME,

the assignee of record for the present application, that discloses a compound number (AME 133) and certain properties for this compound of undisclosed and unknown structure. The Applicants submit that the press release cited by the Examiner represents a disclosure of the Applicants own work and, therefore, does not qualify as prior art under 35 U.S.C. § 102(a). The last sentence of section 706.02(a) of the Manual of Patent Examining Procedure clearly states "[f]or 35 U.S.C. 102(a) to apply, the reference must have a publication date earlier in time than the effective filing date of the application, and must not be applicant's own work." (emphasis added). Furthermore, because the effective filing date of the present application is May 20, 2003, less than a year after the date of publication of the cited reference, the press release does not qualify as prior art under 35 U.S.C. § 102(b). Therefore, contrary to the assertion of the Examiner, the claimed invention was not "known in the art." Accordingly, Applicants respectfully request that the Examiner reconsider the lack of unity objection and withdraw the restriction requirement.

Additionally, the cited disclosure is not an anticipating disclosure because it merely discloses a name and certain properties of a compound of unknown structure. The disclosure given in the press release is not sufficient to destroy novelty of the features of the claimed invention because it does not disclose the structure of the compound referred to as AME-133, whereas the compositions presently claimed comprise CD20 binding molecules comprising light and heavy chain variable regions that are defined by specific amino acid sequences. Evidence introduced to provide descriptive matter not found in a single prior art reference must make clear that the property described by the extrinsic evidence is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill (Continental Can, 20 USPQ2d at 1749-50 (citing In re Oelrich, 212 USPQ 323, 326 (CCPA 1981). Clearly, the specific amino acid sequences defining the claimed subject matter are not necessarily present in the compound described in the press release. And, one

can not reasonably conclude that based on the description in the cited reference, persons of ordinary skill would recognize that the specific amino acid sequences of the claimed subject matter were present in the AME-133 antibody . The Examiner's reliance merely on his own conclusory statements to the contrary, without reference to any relevant rule or legal precedent to support, is insufficient basis for the present restriction requirement. Accordingly, the objection of lack of unity should be withdrawn.

Lastly, the Applicants call the Examiner's attention to Chapter 10, paragraph 4 of the PCT International Search and Preliminary Examination Guidelines:

> Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, **the benefit of any doubt being given to the Applicant**. (emphasis added)

In view of all of the above, Applicants respectfully request that the Examiner reconsider the objection of lack of unity and withdraw the restriction requirement. If the restriction to Groups I and II is maintained, Applicants respectfully request that method of use claims (Group II) be rejoined when a product claim (Group I) is found to be allowable. According to M.P.E.P. §821.04 and In re Ochiai (71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995)), rejoinder of product claims with process claims commensurate in scope with the allowed product claims is permitted following a finding that the product claims are allowable. Accordingly, Applicants have retained claims 40-47 in the enclosed amended claims for potential rejoinder, in light of the traversal.

Applicants also hereby reserve the right to claim any non-elected subject matter in one or more continuations and/or divisional applications.

Applicants do not believe that any additional fees are incurred; however, any additional fees associated with this amendment may be charged to Eli Lilly Deposit Account number: 05-0840.

Applicants courteously request favorable consideration of this application. The Examiner is invited to contact the undersigned attorney should any questions arise as a result of the submission provided herein, or if any question arises at any point during the examination of the present application.

Respectfully submitted,

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